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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P51325 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US03/07509 | International filing date (day/month/year) 12 March 2003 (12.03.2003) | Priority date (day/month/year) 13 March 2002 (13.03.2002) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/4166; C07D 233/78 and US Cl.: 514/389, 391, 392; 548/319.5 | | |
| Applicant SMITHKLINE BEECHAM CORPORATION | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>7</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | |
| Date of submission of the demand 25 September 2003 (25.09.2003) | Date of completion of this report 18 February 2004 (18.02.2004) | |
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer <i>J. Roberts for</i> Laura L. Stockton, Ph.D. Telephone No. 703/308-1235 | |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-15 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 16-17, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the drawings:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Internal application No.
PCT/US03/07509**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

| | | |
|-------------------------------|-----------------------|-----|
| Novelty (N) | Claims <u>2</u> | YES |
| | Claims <u>1 and 3</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-3</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-3</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Applicants' response of 12/09/03 has been considered.

Claims 1 and 3 lack novelty under PCT Article 33(2) as being anticipated by Jacobsen {U.S. Pat. 5,712,300}.

Jacobsen disclose compounds, such as Example 1 in column 2, which is embraced by the instant claims, and that are useful in treating diseases such as periodontitis, gingivitis, etc.

Claims 1-3 lack an inventive step under PCT Article 33(3) as being obvious over Jacobsen {U.S. Pat. 5,712,300}.

Applicant claims 2-imidazolidone and 2-pyrrolidone compounds. Jacobsen disclose compounds, such as Example 1 (column 2) and Example 36 (column 64), which are embraced by the instant claims, and that are useful in treating diseases such as periodontitis, gingivitis, etc. Further, Jacobsen generically describes a number of other 2-imidazolidone and 2-pyrrolidone compounds (columns 2-4). One skilled in the art would have been motivated to prepare additional 2-imidazolidone and 2-pyrrolidone compounds embraced by Jacobsen to arrive at the instant claim compounds (see instant claim 2) with the expectation of obtaining additional beneficial 2-imidazolidone and 2-pyrrolidone compounds which would be useful in treating periodontitis, gingivitis, etc. Therefore, the instant claimed invention would have been obvious to one skilled in the art.

Claims 1-3 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.